

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CINCINNATI, OHIO 45268

SOURCE SELECTION DETERMINATION

Solicitation 68HERC20R0017 – "High Throughput Transcriptomics Using Targeted RNA-Seq (Human and Common Laboratory Species)"

1.0 DETERMINATION/SELECTION

In accordance with FAR 52.215-1, it has been determined that award of the contract resulting from Solicitation 68HERC20R0017 will be made, following clarifying exchanges, to **BioSpyder Technologies, Inc**. This determination is based upon application of the stated evaluation criteria and subcriteria, and the evaluation approach specified in this Solicitation, where all evaluation factors other than cost or price when combined are significantly more important than cost or price, utilizing a "best value" analysis. The findings below support this determination, which is in the best interest of the Government.

2.0 BACKGROUND

The U.S. Environmental Protection Agency (EPA), Center for Computational Toxicology and Exposure (CCTE), has a requirement for a contractor to provide targeted RNA Sequencing (RNA-seq) to evaluate treatment-related changes in gene expression in cells in culture. This includes, but is not limited to, TempO-Seq and TruSeq RNA Exome. Multiplexed assays that measure transcriptomic changes for up to 21,000 protein coding genes using targeted RNA-seq directly on cell lysates or purified RNA samples is expected.

The Government anticipates award of an indefinite delivery/indefinite quantity (ID/IQ) contract that will allow for the issuance of firm fixed price (FFP) type task orders over an ordering period of 5 years. The EPA intends to award a single contract with an ordering ceiling of \$25 Million.

A. Competition

- 1. This procurement was reviewed by an assigned OSDBU Small Business Specialist, as well as the SBA's assigned Procurement Center Representative (PCR) who concurred with the Contracting Officer's recommendation to solicit this requirement under a Total Small Business Set-Aside.
- 2. Diligent efforts were made to avoid restrictive criteria in the Solicitation (SOL). There are no restrictions to subcontracting. No firms indicated that the SOL was unduly restrictive.

3. A Pre-Solicitation Notice was posted to the Federal Business Opportunities (FBO) website on November 20, 2019. The SOL was made available to potential offerors on FBO and via FedConnect on March 19, 2020. The SOL was open for responses for a total period of 35 days.

B. Request for Proposal

One (1) proposal was received by the April 23, 2020 closing date. The proposal received was from BioSpyder Technologies, Inc. (BioSpyder). There were no late proposals. The technical proposal was submitted for technical evaluation on April 25, 2020. During the technical evaluation panel (TEP) consensus meeting held on May 7, 2020, EPA/CAD Contract Specialist Keith Pfeffer provided administrative guidance and assistance, and was present for the proposal evaluation discussions conducted by the TEP. The entirety of the TEP discussions were held via teleconference as a result of the COVID-19 pandemic. The purpose of administrative participation was not to influence the outcome of the TEP deliberations, but to ensure that all discussions made by the TEP were appropriately encompassed by the established evaluation criteria and subcriteria. The final TEP report was accepted by the Contracting Officer on May 16, 2020. The technical evaluation report is filed under Tab 53 of the electronic contract file.

3.0 Evaluation Methods

Proposal evaluation was consistent with the EPA Source Selection Guide (Appendix A and B to EPAAG 15.3.1) as set out in the SOL.

Offerors were informed that all evaluation factors other than cost or price, when combined, are significantly more important than cost or price (see provision M-1 of the SOL). The proposal was evaluated in accordance with the technical evaluation criteria and subcriteria as set forth in provision M-1 of the SOL. The evaluation criteria and subcriteria, listed in descending order of criterion importance, are as follows:

I. Technical Approach

The offeror's technical approach will be evaluated on the demonstrated understanding, knowledge, and capability to perform all requirements of the contract statement of work (SOW). Specifically, offerors must address the following elements, which are considered of equal importance:

- 1. High throughput Capacity The offeror's demonstrated technical approach to using High Throughput Screening to complete the tasks outlined in the SOW to process thousands of samples within the timeframes stated in the SOW.
- 2. Reliable Assays The offeror's demonstrated technical approach to providing reliable assays for measuring changes in RNA expression in cell lysates and purified RNA samples derived from humans and commonly used laboratory test species (i.e. rat, mouse, zebrafish). Demonstrated technical validation of proposed assays for measuring gene

expression in the aforementioned species. Specifically, offerors shall address the following elements:

- Explain the methods and approaches to be used in generating the libraries from cell lysates or purified RNA, quality checking the libraries, sequencing, sequencing alignments, and data normalization.
- Demonstrated multiplexed targeted RNA-sequencing capability for up to 20,000 21,000 protein coding genes and the ability to evaluate a smaller number of specific genes to decrease price/increase throughput
- Demonstrated targeted RNA-sequencing capability directly from cell lysates and purified RNA
- Demonstrated sample barcoding and deconvolution for sequencing samples, and explain overall strategy for pooling barcoded samples from 96- and 384-well plate formats (e.g. number of samples per pool, number of sequencing lanes/runs per pooled library)
- Demonstrated use of quality control criteria for assessing assay performance.
- Demonstrated accuracy of the technical approach at sequencing depths proposed in the pricing chart and in relation to non-targeted RNA-Seq.
- Demonstrated capability for attenuating signal from highly expressed genes
- 3. Laboratory Practices The offeror's demonstrated technical approach to employing sound laboratory practices, including the handling and tracking of samples, and strategy for pooling barcoded samples to achieve approximately equal sequencing depth per sample. Ability to perform required analysis with a minimal quantity of sample required for assays proposed. Ability to deliver data of consistent integrity and format.

II. Technical Qualifications, Education, Experience, and Expertise of Key Personnel

The offeror's Key Personnel will be evaluated on the extent to which they possess the appropriate technical education, experience, and expertise to perform the tasks described in the SOW. The technical qualifications of key personnel shall be evaluated through information provided in the Technical Proposal and key personnel résumés. ONLY the primary candidate (no deputies, backups, etc.) will be factored into the key personnel position evaluations.

The key personnel positions for this requirement are

- Program Manager
- Senior Laboratory Scientist
- Bioinformatics Scientist

III. Past Performance

The offeror's past performance will be evaluated on the demonstrated quality of the offeror's performance of up to five (5) contracts and subcontracts performed during the past three (3) years, which are of similar in nature to this requirement terms of technical scope, and magnitude (dollar amount). The following items will be considered when evaluating the offeror's past performance: Quality of Product or Service; Cost Control; Timeliness of Performance; Business Relations; and Customer Satisfaction.

Offerors with no past performance history, whose past performance is not relevant, or for whom past performance data is not available, will be given, a neutral rating of adequate.

IV. Quality Management Plan (QMP)

The offeror's QMP will each be evaluated by the Quality Assurance Manager of CCTE on whether it meets all of the requirements of FAR 52.246-11, Higher-Level Contract Quality Requirement (Government Specification). Plans that meet all requirements will be rated "Pass", plans that do not meet all requirements will be rated "Fail". An offeror whose QMP is rated as "Fail" at time of award will be ineligible for award.

Documents specifying the requirements and guidance for developing the QMP can be found at EPA's website for QMPs (http://www.epa.gov/quality/epa-qar-2-epa-requirements-quality-management-plans). In accordance with EPA QA/R-2 Section 3.2, in order to be acceptable, the QMP must document the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data, and indicate how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan assess, and improve the organization's quality system.

Technical Evaluation

Source selection under this Solicitation shall be based upon application of the stated Solicitation evaluation criteria, where all evaluation factors other than cost or price when combined are significantly more important than cost or price, and the utilization of a "best value" assessment, including any applicable cost-technical trade-off analysis.

The TEP assigned a technical/risk rating for each of the evaluation factors listed in the Technical Evaluation Criteria for the competition. Except for Past Performance, the following adjectival ratings were used in the evaluation of all technical criterion:

	Combined Technical/Risk Rating
Rating	Description
Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses do not outweigh one another or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal does not clearly meet requirements and has not clearly demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not outweighed by strengths. Risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is unacceptable for purposes of an award

The EPA will use the ratings below in its evaluation of the past performance factor:

	Performance Confidence Assessment
Rating	Description
Substantial	Based on the offeror's recent/relevant performance record, the
Confidence	Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory	Based on the offeror's recent/relevant performance record, the
Confidence	Government has a reasonable expectation that the offeror will
	successfully perform the required effort.
Limited	Based on the offeror's recent/relevant performance record, the
Confidence	Government has a low expectation that the offeror will successfully
	perform the required effort.
No Confidence	Based on the offeror's recent/relevant performance record, the
	Government has no expectation that the offeror will be able to
	successfully perform the required effort.
Unknown	No recent/relevant performance record is available or the offeror's
Confidence	performance record is so sparse that no meaningful confidence assessment
(Neutral)	rating can be reasonably assigned.

- (1) Criterion I 'Technical Approach' is the technical criterion of highest importance, with subelements 1, 2, & 3 of equal importance followed in level of importance by;
- (2) Criterion II 'Technical Qualifications of Key Personnel', followed in level of importance by;
- (3) Criterion III 'Past Performance'.

EPA will use a 'Pass' or 'Fail' rating in its evaluation of Criterion IV, the Quality Management Plan criterion. The Quality Management Plan will be evaluated for acceptability only. A proposal that fails to meet the standards set forth in the Section L provision, EPA-L-46-101, "Instructions for the Preparation of a Quality Management Plan," and the Section E clause FAR 52.246-11, "Higher Level Contract Quality Requirements," cannot be considered for award.

A table of the adjectival technical rating results for the proposal is set forth below:

Criterion	Relative	BioSpyder Technologies, Inc.
	Importance	
	Ranking	
1 – Technical Approach		
	First	Individual Subcriteria Ratings Only (below)
1(A) High Throughput	Equal to all	(b)(5)
Capacity	other Criterion	
capacity	1 Subcriteria	
1(B) Reliable Assays		
	Equal to all	
	other Criterion	

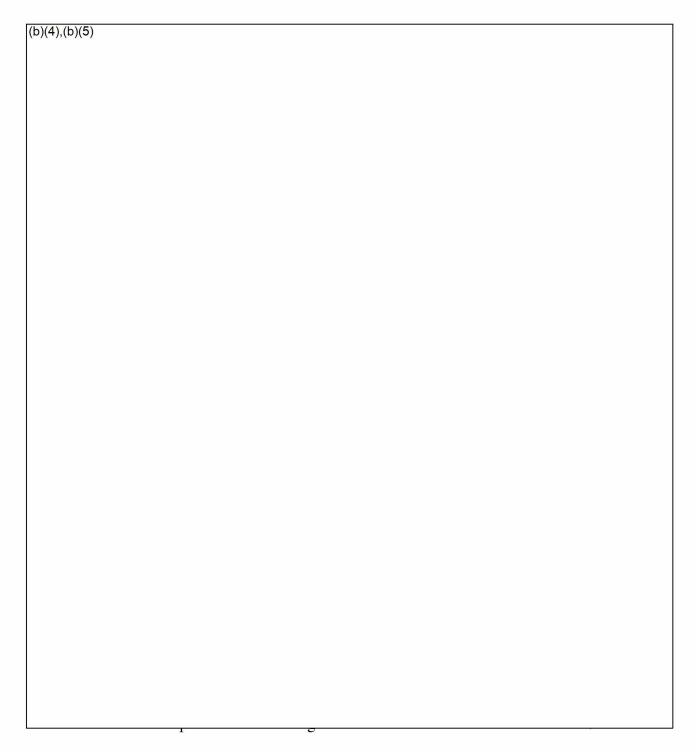
1(C) Laboratory Practices	1 Subcriteria Equal to all other Criterion 1 Subcriteria	(b)(4)
2 – Technical Qualifications, Education, Experience, and Expertise of Key Personnel	Second	Individual Subcriteria Ratings Only (below)
2(A) – Program Manager	Equal to all other Criterion 2 Subcriteria	(b)(5)
2(B) – Senior Laboratory Scientist	Equal to all other Criterion 2 Subcriteria	
2(C) – Bioinformatics Scientist	Equal to all other Criterion 2 Subcriteria	
3 – Past Performance 4 – Quality Management Plan (QMP)	Third Pass/Fail	

4.0 ANALYSIS OF PROPOSAL

This section provides the individual technical criteria/subcriteria and the ratings, along with a broad rating rationale for each criteria/subcriteria. More detailed strengths/weaknesses/risks narratives can be referenced in the technical evaluation report, filed under Tab 53 of the electronic file.

The content in this section is based on information gathered through proposal analysis, along with additional information received through clarifications with the sole offeror. Despite receiving only this one (1) proposal, both the Contracting and Program offices determined that several clarifications were necessary in order to be able to adequately evaluate the offeror's proposal. Clarifications were sought both to resolve baseline responsibility matters as well as proposal ambiguities not impacting overall price. These exchanges were as follows:

(b)(4),(b)(5)		



Evaluation of the Solicitation's stated Technical Evaluation Criteria is as follows:

I. Technical Approach

The offeror's technical approach will be evaluated on the demonstrated understanding, knowledge, and capability to perform all requirements of the contract statement of work (SOW).

Specifically, offerors must address the following elements, which are considered of equal importance:

A. High throughput Capacity – The offeror's demonstrated technical approach to using High Throughput Screening to complete the tasks outlined in the SOW to process thousands of samples within the timeframes stated in the SOW.

(b)(4),(b)(5)

- **B. Reliable Assays** The offeror's demonstrated technical approach to providing reliable assays for measuring changes in RNA expression in cell lysates and purified RNA samples derived from humans and commonly used laboratory test species (i.e. rat, mouse, zebrafish). Demonstrated technical validation of proposed assays for measuring gene expression in the aforementioned species. Specifically, offerors shall address the following elements:
 - Explain the methods and approaches to be used in generating the libraries from cell lysates or purified RNA, quality checking the libraries, sequencing, sequencing alignments, and data normalization.
 - Demonstrated multiplexed targeted RNA-sequencing capability for up to 20,000 21,000 protein coding genes and the ability to evaluate a smaller number of specific genes to decrease price/increase throughput
 - Demonstrated targeted RNA-sequencing capability directly from cell lysates and purified RNA
 - Demonstrated sample barcoding and deconvolution for sequencing samples, and explain overall strategy for pooling barcoded samples from 96- and 384-well plate formats (e.g. number of samples per pool, number of sequencing lanes/runs per pooled library)
 - Demonstrated use of quality control criteria for assessing assay performance.
 - Demonstrated accuracy of the technical approach at sequencing depths proposed in the pricing chart and in relation to non-targeted RNA-Seq.
 - Demonstrated capability for attenuating signal from highly expressed genes

(b)(4),(b)(5)
C. Laboratory Practices – The offeror's demonstrated technical approach to employing sound laboratory practices, including the handling and tracking of samples, and strategy for pooling barcoded samples to achieve approximately equal sequencing depth per sample. Ability to perform required analysis with a minimal quantity of sample required for assays proposed. Ability to deliver data of consistent integrity and format.
(b)(4),(b)(5)

(b)(4),(b)(5)
The bound of the state of the s
II. Technical Qualifications, Education, Experience, and Expertise of Key Personnel
The offeror's Key Personnel will be evaluated on the extent to which they possess the appropriate
technical education, experience, and expertise to perform the tasks described in the SOW. The
technical qualifications of key personnel shall be evaluated through information provided in the
Technical Proposal and key personnel résumés. ONLY the primary candidate (no deputies,
backups, etc.) will be factored into the key personnel position evaluations.
(b)(4),(b)(5)
(b)(4),(b)(5)

(b)(4),(b)(5)
(b)(4),(b)(5)
III. Past Performance
111. Tast renormance
The offeror's past performance will be evaluated on the demonstrated quality of the offeror's performance of up to five (5) contracts and subcontracts performed during the past three (3) years, which are of similar in nature to this requirement terms of technical scope, and magnitude (dollar amount). The following items will be considered when evaluating the offeror's past performance: Quality of Product or Service; Cost Control; Timeliness of Performance; Business Relations; and Customer Satisfaction.
Offerors with no past performance history, whose past performance is not relevant, or for whom past performance data is not available, will be given, a neutral rating of adequate.
(b)(4),(b)(5)

IV. Quality Management Plan (QMP)

The offeror's QMP will each be evaluated by the Quality Assurance Manager of CCTE on whether it meets all of the requirements of FAR 52.246-11, Higher-Level Contract Quality Requirement (Government Specification). Plans that meet all requirements will be rated "Pass", plans that do not meet all requirements will be rated "Fail". An offeror whose QMP is rated as "Fail" at time of award will be ineligible for award.

Documents specifying the requirements and guidance for developing the QMP can be found at EPA's website for QMPs (http://www.epa.gov/quality/epa-qar-2-epa-requirements-quality-management-plans). In accordance with EPA QA/R-2 Section 3.2, in order to be acceptable, the QMP must document the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data, and indicate how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan assess, and improve the organization's quality system.

(b)(4),(b)(5)	

5.0 PRICE ANALYSIS

For proposal evaluation purposes, Attachment 2 to the Solicitation, titled Pricing Worksheets, contained a series of pricing sheets that offerors were instructed to complete. As detailed in Solicitation provision L-6, titled PROPOSAL INSTRUCTIONS, offerors were required to submit all-inclusive, fixed-price rates for each cost unit across the provided pricing worksheets. The totality of these costs, added together, represents the total firm-fixed price proposed for the contract.

(b)(4),(b)(5)		

(b)(4),(b)(5)	
(b)(5)	
(b)(4),(b)(5)	
(b)(4),(b)(5)	

(b)(4),(b)(5)	
(b)(4),(b)(5)	1

6.0 PROPOSAL SUMMARY AND RATIONALE FOR AWARD

For purposes of proposal evaluation, all evaluation factors other than cost or price, when combined are significantly more important than cost or price.

As detailed above, the technical evaluation, price analysis, and past performance evaluation collectively support award of the contract to BioSpyder. BioSpyder was the sole offeror in response to the Solicitation, and as such, was the only proposal considered for award. The Agency's TEP performed a detailed evaluation of the offeror's technical proposal, which returned consensus ratings indicative of a likelihood of successful contract performance.
(b)(4),(b)(5)
As a result, it is the Source Selection Official's (SSO) determination that BioSpyder offers the best value, and that award to BioSpyder is in the Government's best interest. This determination is consistent with the Solicitation, which states that all evaluation factors, other than cost or price when combined are significantly more important than cost or price, and with the evaluations of the offeror's proposal in accordance with the Solicitation requirements and evaluation criteria and subcriteria. Thus, it is in the Government's best interest to award a contract resulting from this Solicitation to BioSypder.
7.0 OTHER AREAS (b)(4)

(D)(4)

7.0. CONCLUSION

- A. I am certain the proposal evaluation process was properly handled in compliance with the evaluation criteria. In addition, I am equally confident the proposal review process was conducted thoroughly and completely, with the utmost integrity of the personnel involved, and in complete accord with the personal COI and non-disclosure agreements signed by these same personnel.
- B. I have reviewed the technical evaluation report, the price analysis report, the contractor's past performance information, and the contractor's proposal. My selection determination is based upon a review of these documents, discussions with advisors and technical team personnel, and an assessment of the proposal against the SOL evaluation criteria and subcriteria. I highly considered the evaluation reports and the information provided to me from the technical evaluation team; however, the award decision represents my own independent judgment.
- C. I agree with the overall technical evaluation and ratings provided by the technical evaluation team.
- D. BioSpyder's proposal was found to offer appropriate technical merit at a fair and reasonable price, with relevant and positive past performance information. BioSpyder has been found to be responsible in accordance with the Solicitation. In addition, there are no other known factors which would preclude award to BioSpyder.
- E. Based on my authority as the Source Selection Official (SSO), I determine award to BioSpyder, at the proposed total ceiling price of \$25,000,000.00, to be fair and reasonable.

Although BioSpyder's total propo	esed price was (b)(4)	(b)(5)		
(b)(5)	both the Agency and BioSpyd	er acknowledged during the SOL		
process that the contract's maxim	um ceiling would be \$25,000,0	000.00. As a result of the totality		
of the above analysis, BioSpyder has been determined to offer the best value to the Government,				
with cost and technical merit cons	sidered.			

SOURCE SELECTION DETERMINATION

SOL 68HERC20R0017

High Throughput Transcriptomics Using Targeted RNA-Seq (Human and Common Laboratory Species)

PREPARED BY:	Keith Pfaffer	6/17/2020	
PREPARED BY:	Keith Pfeffer	Date	
	Contract Specialist OAS/CAD/ORD/Pre-Award Team		
REVIEWED BY:	KATHLEEN ROE Digitally signed by KATHLEEN ROE Date: 2020.06.17 12:11:49 -04'00'		
REVIEWED D1.	Kathleen Roe Branch Chief OAS/CAD/ORD	Date	
APPROVED BY:	Matthew J Growney	6/17/2020	
	Matthew Growney	Date	
	Source Selection Official		
	OAS/CAD/ORD/Pre-Award Team		